UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO.                                      | FILING DATE                     | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|---------------------------------|----------------------|---------------------|------------------|
| 10/589,054   | 04/01/2008                      | Christopher J Soares | 0105US-UTL2         | 5466             |
|  | 7590 02/11/201 perty Department | EXAMINER             |                     |                  |
| Amylin Pharmaceuticals, Inc. 9360 Towne Centre Drive |                                 |                      | HOWARD, ZACHARY C   |                  |
| San Diego, CA 92121                                  |                                 |                      | ART UNIT            | PAPER NUMBER     |
|  |                                 |                      | 1646                |                  |
|  |                                 |                      |                     |                  |
|  |                                 |                      | NOTIFICATION DATE   | DELIVERY MODE    |
|  |                                 |                      | 02/11/2011          | ELECTRONIC       |

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@amylin.com trademarks@amylin.com



## United States Patent and Trademark Office

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, DC 2023

| APPLICATION NO. /CONTROL NO. | FILING DATE | FIRST NAMED INVENTOR / PATENT IN REEXAMINATION | ATTORNEY DOCKET NO. |
|------------------------------|-------------|--|---------------------|
| 10589054                     | 4/1/08      | SOARES ET AL.                                  | 0105US-UTL2         |

**EXAMINER** ZACHARY C. HOWARD

| ART UNIT | PAPER    |  |
|----------|----------|--|
| 1646     | 20110204 |  |

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

## **Commissioner of Patents**

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

The 5/12/10 Office Action, at pg 2-3 contained a section titled "Sequence Compliance" that indicated lack of sequence compliance for the following reasons:

"Specifically, "formula I" in claim 5, and in the specification at ¶ [0087] (as published), is identified as SEQ ID NO: 34, but does not match SEQ ID NO: 34 in the Sequence Listing (filed 6/19/08). Specifically, in SEQ ID NO: 34, residues 2 and 7 are identified as "any amino or not present", but in "formula I", residues 2 and 7 are only identified as "X" and "Y"."

Applicants' 11/16/10 amendments to the claims, once entered, will render this moot with respect to claim 5 (which is indicated as being canceled). However, SEQ ID NO: 34 in the Sequence Listing still does not match SEQ ID NO: 34 as shown in the specification at page 5, as described above.

In the 11/16/10 response, Applicants argue that the present sequence listing does comply with the sequence rules. Applicants argue that X and Y are not amino acids and thus SEQ ID NO: 34 cannot identify residues 2 and 7 as X and Y, respectively. Applicants argue that the specification at paragraph 90, 109 and 139 indicates that residue 2 (X) and 7 (Y) can be any amino acid.

Applicants' arguments have been fully considered and are found persuasive in part. Paragraphs 109 and 139 of the specification teach X and Y residues that are specific to other sequences (e.g., SEQ ID NO: 5) and do not refer to SEQ ID NO: 34. Only paragraph 90 describes the X and Y for SEQ ID NO: 34. However, it is found persuasive that "Any amino acid" as used in the Sequence Listing is sufficient to describe X and Y of SEQ ID NO: 34 of the specification, in view of the teachings of paragraph 90. However, nowhere does paragraph 90 (or anywhere else in the specification) indicate that X and Y of SEQ ID NO: 34 can be "not present". Thus, the Sequence Listing must be amended to remove "or not present" from residues 2 and 7 of SEQ ID NO: 34.

APPLICANT IS GIVEN ONE MONTH FROM THE DATE OF THIS LETTER WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 C.F.R.. §§ 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 C.F.R. § 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

The addresses below are effective 5 June 2004. Please direct all replies to the United States Patent and Trademark Office via one (1) of the following:

1. Electronically submitted through EFS-Web (<a href="http://www.uspto.gov/ebc/efs/downloads/documents.htm">http://www.uspto.gov/ebc/efs/downloads/documents.htm</a>, EFS Submission User Manual - ePAVE)

2. Mailed to:

Mail Stop Sequence Commissioner for Patents P.O. Box 22313 1450

Alexandria, VA 22313 1450

3. Hand Carry, Federal Express, United Parcel Service or other delivery service to:

U.S. Patent and Trademark Office

Mail Stop Sequence

Customer Window

Randolph Building

401 Dulaney Street

Alexandria, VA 22314

Any inquiry concerning this communication should be directed to Zachary C. Howard at telephone number (571)272-2877. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, can be reached on (571)272-0835

/Bridget E Bunner/ Primary Examiner, Art Unit 1647